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REMARKS

This Amendment responds to the final office action mailed February 27, 2007 (the Office Action). The Office Action was carefully reviewed and the following remarks are intended to fully address the concerns raised therein. There a multiple independent reasons for allowing the claims; careful consideration of each of the arguments is requested.

As explained at the end of remarks, it seems clear that a new office action should be provided if the claims are not allowed.

Status of Claims

Claims 1-10 and 13-25, 27, and 29-62 are pending. Claims 17-25, 27, and 29-38 and 62 are under examination. Claim 42 is cancelled without prejudice for future prosecution.

Withdrawn claims 1 and 39 are amended for consistency with the claims under active prosecution. Withdrawn claim 41 is amended for a typographic error and clarity. Withdrawn claim 56 was amended for antecedent basis. Claim 17 is amended to specify a radiation dose of at least 70 Gy as per the specification at, e.g., page 20, line 8. Claim 17 was further amended to clarify that it is the device that degrades, e.g., as at Example 2 of the specification.

New claim 63 was added, with support in the specification at, e.g., page 5, line 17.

Status of Withdrawn Claims

Claims 1-10, 13-16, and 39-61 have been withdrawn by the Examiner. Claims 33 and 35 are linking claims that link the inventions of Groups I, III, and IV. Applicant has elected Group IV having claims 17-38, and made a species election of item (h) polyethylene glycol.

Withdrawn claims are not cancelled herein

The Examiner states that the nonelected claims must be cancelled (page 8 of the Office Action) as per 37 C.F.R. §1.144 and MPEP §821.01. The withdrawn claims do not require cancellation, however, because they are linked by generic claims 33 and 35. The status of these claims as generic was established by the Patent Office and is of record in the restriction requirement dated June 23, 2006.

MPEP §821 explains that §§821.01 - 821.04 control claims held to be drawn to nonelected inventions, including claims drawn to nonelected species or inventions that may be eligible for rejoinder. MPEP §821.04 explains that "when all the claims directed to the elected invention are in condition for allowance, and the nonelected invention(s) should be considered for rejoinder." It is only when the withdrawn claims are ineligible for rejoinder that their cancellation is required. Rejoinder of the withdrawn claims is requested upon allowance of the generic claims.

Discussion

The undersigned discussed the case with the Examiner on about March 15, 2007 to determine if adding radiation dosage amounts would address her concerns since this seemed to be the major point of objection to the claims. The Examiner declined to state whether or not such an amendment would facilitate prosecution of the case and indicated that she would only consider formally presented amendments. The discussion did not involve other aspects of the case.

Rejection of claims

Claims 17-25, 27, 29-38 and 62 were rejected under 35 U.S.C. §103(a) as being unpatentable over Tihon et al. (U.S. Pat. No. 5,499,994) and Gokcen (U.S. Pat. No. 6,913,744).

This rejection represents a renewal of a previous rejection in spite of Applicant's previous amendments of record.

The Office Action's basis for the rejections

The Office Action sets forth its rejection of the claims by first explaining its reasoning (pages 3-5) and then addressing the Applicant's previous arguments (pages 6-7). Each of its points are taken in the order presented in the Office Action.

(1) The cited art teaches the opposite of the claimed tissue displacement

The Office Action characterizes Tihon et al. as teaching treatment of hypertrophy of the prostate gland and dilation devices or swellable materials for the urethra (Office Action page 3) and describes the swellable aspect at pages 3-4 of the Office Action. The Office Action characterizes Gokcen as teaching a method and composition for treating prostate cancer whereby suitable methods of treatment disclosed include administering radiation (Office Action page 4) and active agents such as antibiotics (Office Action page 4-5).

A prima facie case of rejection must supply every claimed element. The Office Action's rejection necessarily requires that the urethra and the prostate are supplying the claimed first tissue and second tissue. The Office Action does not explain, however, how this could possibly provide the claimed (claim 17) aspect of introducing a biocompatible, biodegradable filler to between a first tissue location (prostate) and a second tissue location (urethra) to increase a distance between the first tissue location (prostate) and the second tissue location (urethra). In fact, Tihon et al. teaches a device that is placed inside a urethra that does not increase a distance between any one tissue and any another tissue, and certainly not a distance between a urethra and a prostate gland. Specifically, Tihon et al. teaches a device 22, see Figures 2 and 3, that is placed inside urethra 12 that expands in response to swelling of hydrophilic means 32. The device is

inside the urethra and therefore forces the urethra against the surrounding tissue. The device thus apparently does not increase a distance between a first and a second tissue. In fact, it apparently presses the urethra against the prostate and decreases the distance between these two tissues and does the *exact opposite* of what is claimed.

For these reasons, it is respectfully submitted that no prima facie case of obviousness has been made and withdrawal of the obviousness rejection is requested.

(2) The cited art teaches the opposite of the claimed biodegradable filler

Amended claim 17 states that a biocompatible, biodegradable filler device is removed by biodegradation of the filler device in the patient. Tihon et al. and Gokcen do not teach or suggest this feature in combination with the other claimed features.

Tihon et al. describes only devices that are not degradable and are not removed by biodegradation, regardless of whether or not the devices have degradable materials captured therein. For instance, Tihon et al. explains that a hollow member 24 and a covering 33 (see Tihon et al. Figure 3) are part of the device; these elements are not degradable. Tihon et al. explains that the device must be removed, e.g., at column 9 lines 61-67, something that must be done regardless of the use of other materials interior to the device.

For these reasons, withdrawal of the obviousness rejection is requested.

(3) There is no motivation to combine the cited art

It is agreed that Tihon et al. do not teach administering radioactivity or applying an antibiotic to a tissue (Office Action page 4).

The Office Action provided the following explanation for combining the references:

> "It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the radiation methods and active agents, such as antibiotics, as taught by Gokcen within the treatment methods of Tihon et al. One of ordinary skill in that art would be motivated to do so with a reasonable expectation of success because Gokcen teaches that suitable and effective methods for treatment of prostate cancer include [sic] administering radiation, dependent on factors such as age of patient and severity of condition and also teach that active agents, such as antibiotics are added to the composition to promptly relieve symptoms of acute prostatic infections. The expected result would be an improved, safe and effective method for treating prostatic conditions in a patient."

The Office Action states that it would have been obvious to combine the references "because Gokcen teaches that suitable and effective methods for treatment of prostate cancer include [sic] administering radiation, dependent on factors such as age of patient and severity of condition and also teach that active agents, such as antibiotics are added to the composition to promptly relieve symptoms of acute prostatic infections." But it is not enough to describe what Gokcen teaches. There must be a reason to combine Gokcen with Tihon et al. It is a well-settled principle that just because references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. See MPEP 2143.01. Withdrawal of this rejection is requested.

(4) The claims are not diminished by relative terminology

The Examiner indicated that the claim language "administering a dose [of at least 70 Gy] of radioactivity to the second tissue location so that the presence of the filler causes the first

tissue location to receive less of the dose of radioactivity compared to the amount of the dose of radioactivity the first tissue location would receive in the absence of the filler" is relative in nature and thus lacks patentable weight. This language, however, is clear and definite and thus has patentable weight, as explained below. There is no legal basis for not giving patentable weight to a clear and definite limitation in a method claim.

MPEP §2173.05 entitled "Relative Terminology" provides some guidance in this situation. It states that "The fact that claim language, including terms of degree, may not be precise, does not automatically render the claim indefinite under 35 U.S.C. 112, second paragraph." The MPEP points out that the standard for judging this language is that "Acceptability of the claim language depends on whether one of ordinary skill in the art would understand what is claimed, in light of the specification."

The claim language in this case is clear and definite to those of ordinary skill because the claim plainly states a test that can be performed. The test is that the presence of the filler causes the first tissue location to receive less of the dose of radioactivity compared to the amount of the dose of radioactivity the first tissue location would receive in the absence of the filler. Thus the artisan can compare the amount of radiation that the first tissue location receives in the presence and absence of the filler.

This comparison as claimed is clear and definite, as documented in the specification. In the situation wherein the first tissue location is a rectum and the second tissue location is a prostate gland that is being treated with the radiation (claim 18), then the amount of radiation received at the rectum can be calculated or measured in the presence and absence of the filler. Example 2 describes exactly this situation. A trial was made involving 10 men who received fillers to displace the rectum away from the prostate prior to proceeding with their radiotherapy. The radiation dose to the rectum was diminished by an amount that could be determined with clarity and definiteness (approximately 50%).

Accordingly, since this limitation is clear and definite, an examination of the claims that provides patentable weight to this limitation is requested.

(5) Claimed comparison of radioactivity dose

As previously argued, Tihon et al. and Gokcen do not teach or suggest, among other things, the limitation of claim 17 directed to using the filler to increase a distance between the first tissue location and the second tissue location so that the presence of the filler causes the first tissue location to thereby receive less of a dose of radioactivity that is applied. Therefore there is no prima facie case of obviousness since each and every claimed limitation is not present in the prior art.

The Office Action addresses this argument by arguing that this limitation has no patentable weight. As explained above, however, this limitation should be given patentable weight such that the claims should be allowed.

(6) Radiation dose

The claims are amended herein to specify a dose of radiation of at least 70 Gy so as to address the concerns that the Examiner expressed in the Office Action at the sentence bridging pages 6-7 that the "dose" was rather vague and unspecific. Although the claims are amended to facilitate prosecution, it is maintained that a "dose" has a meaning understandable to those practicing these arts and is not vague or unspecific.

A basis for rejecting the dependent claims is requested.

The previous Amendment specifically requested a detailed examination of the dependent claims. Unfortunately, no such analysis was presented. The claims can not be legitimately rejected, however, in the absence of prior art that provides every claimed element.

A new Office Action is requested that specifically addresses each dependent claim is requested since, with all due respect, *there is no legal basis in the record that provides a basis for rejecting these claims.*

To facilitate the examination that is legally required for these claims, a discussion of certain of the claims is provided:

Dependent claim 18 specifies that the first tissue location is associated with the rectum and the second tissue location is associated with the prostate gland. The record does not explain why the cited references disclose these claimed elements.

Dependent claim 19 specifies that the filler is introduced into Denovillier's space. The record does not explain why the cited references disclose these claimed elements.

Dependent claim 20 specifies that the first tissue location is located on a tissue that is a member of the group consisting of an ovary, a nerve, a cartilage, a bone, and a brain. The record does not explain why the cited references disclose these claimed elements.

Dependent claim 24 specifies that the filler is biodegradable in vivo in less than approximately 90 days. The record does not explain why the cited references disclose these claimed elements.

Dependent claim 24 specifies that the filler occupies a volume in the range of about 10 to about 200 cubic centimeters in a patient. The record does not explain why the cited references disclose these claimed elements.

Request for allowance

Multiple reasons that are solely dispositive for allowance of the claims are presented. Accordingly, allowance of the claims is requested. The Examiner is invited to telephone the undersigned if the Examiner believes it would be useful to advance prosecution.

Respectfully submitted,

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